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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,167	10/12/2004	Helen Lee	37945-0073	9058

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,167	LEE ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *7-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/23/2004 and 12/12/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

3. The information disclosure statement filed on 12/2/2006 and 6/23/2004 has been considered. Initialed copies are enclosed.

Election/Restrictions

4. Applicant's election with traverse of Group 1, claims 1-17, in the reply filed on 4/20/2007 are acknowledged. The traversal is on the ground(s) that Applicants respectfully disagree with the examiner with the response to election/restriction remarks filed on 5/3/2007. Applicants respectfully disagree with Biswas et al of carrying out a diagnostic method in the presence of DNase. This is not found persuasive because claim 1 and independent and all dependent claims are drawn to a method of treatment that recites the phrase "diagnostic method in the presence of DNase". However the Examiner interprets said claim 1 an independent claim and all dependent claims are drawn to the method of treatment in the presence of DNase. Therefore Biswas et al does teach the presence of DNase and Tarkowski et al teach liquid-based cytology samples from cervical cell lines therefore Tarkowski et al anticipate an endocervical fluid sample. The requirement is still deemed proper and is therefore made FINAL.

Claims 18-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group 2 (claims 18-22), there being no

allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement filed on 5/3/2007.

Claim Objections

5. Claims 7-17 are objected to under 37 CFR 1.75(c) as being in improper form because the claims are dependent from a multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 7-17 have not been further treated on the merits and are withdrawn from consideration.

Claim Rejections - 35 USC § 112

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claim 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

As to claim 1 independent claim and all dependent claims 2-6. Claim 1 is drawn to a method for treatment of a human patient sample for carrying out a diagnostic method on the sample for detection of an infectious agent, wherein the sample is an endocervical fluid sample or a vaginal fluid sample, which includes the step of carrying out the diagnostic method in the presence of DNase. However there are no method steps therefore do not lead to stated method goal.

8. As to claims 2-6 dependent claims, the phrase "preferably" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "preferably"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Biswas et al. 1997, Journal of Clinical Microbiology 35, 1560-1564.

The claim is drawn to a drawn to a method for treatment of a human patient sample for carrying out a diagnostic method on the sample for detection of an infectious agent, wherein the sample is an endocervical fluid sample or a vaginal fluid sample, which includes the step of carrying out the diagnostic method in the presence of DNase.

Biswas et al. teaches a method for treatment of a human patient sample (cervical brush smears) (see pg. 1560 paragraph 1-3) for carrying out a diagnostic method on the sample for detection of an infectious agent (HPV-16 E5) (see pg. 1567 "Results section"), wherein the sample is an endocervical fluid sample or a vaginal fluid sample, which includes the step of carrying out the diagnostic method in the presence of DNase, wherein the DNase is present in an amount of 5U in 10 μl (see "Materials and Methods").

10. Claims 1 are rejected under 35 U.S.C. 102(b) as being anticipated by MacDonald et al. US Patent No. 5,716,793 Date February 1998.

The claim is drawn to a method for treatment of a human patient sample for carrying out a diagnostic method on the sample for detection of an infectious agent, wherein the sample is an endocervical fluid sample or a vaginal fluid sample, which includes the step of carrying out the diagnostic method in the presence of DNase.

MacDonald et al teach a method for treatment of a human patient sample for carrying out a diagnostic method on the sample for detection of an infectious agent (Chlamydia), wherein the sample is an endocervical fluid sample or a vaginal fluid

sample, which includes the step of carrying out the diagnostic method in the presence of DNase (see abstract, column 8 lines 14-34, column 16 lines 55-65).

11. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biswas et al 1997, Journal of Clinical Microbiology 35, 1560-1564 in view of Holt et al TWGDAM Validation May 2001 pgs. 66-67.

Biswas et al is relied up as set forth supra. However Biswas et al does not teach DNase present in an amount of more than 0.5 μg/ml, preferably 0.5 to l00 μg/ml.

Holt et al teach partially degraded DNA samples from blood and saliva samples were prepared using 0.005 units/μl of DNase I.

As to the limitation dependent claim 3, the DNase present in an amount of more than 0.5 μg/ml, preferably 0.5 to l00 μg/ml. According to section 2144.05 of the MPEP, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

A particular parameter must first be recognized as a result-effective variable, i.e., a variable, which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the instant application, the amount of Holt et al. produced a recognized result. Therefore, determining other optimum or workable amounts is routine experimentation.

It would have been prima facie obvious at the time the invention was made to modify the method of treatment in the presence of DNase as taught by Biswas et al to

optimize the amount of the DNase because Biswas et al and Holt et al teach treatment with DNase in bodily fluids.

12. Claims 1, 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacDonald et al. US Patent No. 5,716,793 Date February 1998 in view of Switchenko et al US Patent No. 5,563,038 Date October 8, 1996.

Macdonald et al is relied up as set forth supra. However Macdonald et al does not teach a method for preparation, which includes the step of treating the sample with an oxidizing agent, wherein the oxidizing agent is hydrogen peroxide (H202), wherein a working concentration of hydrogen peroxide is of 0.5% to 3% w/v.

Switchenko et al teach a method for detecting the antigens in a clinical swab sample (Chlamydia) whereby the cell membrane components that are separated by solubilization with detergents such as oxidizing agent hydrogen peroxide can be reconstituted. Switchenko et al teach that antigens can be separated from cellular debris and biological fluids by detergents such as oxidizing agent hydrogen peroxide. Switchenko et al teach solubilization thereof can be accomplished in accordance with the present invention by incubation of the (Chlamydia) bacterial sample in the presence of a detergent such as oxidizing agent hydrogen peroxide as described above, usually in the concentration range of from about 0.01 to 1.0%, weight to volume. Switchenko et al teach one aliquot was combined with sufficient H_2O_2 to yield a final concentration of 1%. (see abstract column 7 lines 17-67, column 8, column 9 lines 40-47, column 18 Example 4).

As to the limitation dependent claim 6, a working concentration of hydrogen peroxide is of 0.5% to 3% w/v. According to section 2144.05 of the MPEP, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of

scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

A particular parameter must first be recognized as a result-effective variable, i.e., a variable, which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the instant application, the amount of Switchenko et al. produced a recognized result. Therefore, determining other optimum or workable amounts is routine experimentation.

It would have been prima facie obvious at the time the invention was made to modify the method of treatment taught by MacDonald et al with incorporating method step of treating the sample with an oxidizing agent and optimize the amount of the hydrogen peroxide as taught by Switchenko et al because MacDonald et al and Switchenko et al both teach methods for detecting the presence of Chlamydia.

Status of the Claims

13. No claims are allowed.

Claims 1-6 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner
GAU 1645
REM 3B31

MARK NAVARRO
PRIMARY EXAMINER